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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/156,952 | 09/18/1998 | ROY A. OSTGAARD | CYM-025 | 1770 |

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EXAMINER

BEX, PATRICIA K

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1743

DATE MAILED: 06/05/2002

29

Please find below and/or attached an Office communication concerning this application or proceeding.

MF-29

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/156,952 | Applicant(s) OSTGAARD ET AL. | |
| | Examiner P. Kathryn Bex | Art Unit 1743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10 and 12-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10 and 12-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>28</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 08, 2002 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-8, 10, 12-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, now recites " the anti-rotation lug comprising...the lowermost edge located substantially remote from the closed end." The term "remote" is a relative term which renders the claim indefinite. The term "remote" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant relies on Figs. 1-2, 4-5 for support the various features of the lugs, however, the specification simply defines the lugs as approximately 1/8 of an inch in height and 1/16 of an inch in width, see page 12, lines 23-26. There is *no mention* of how far the lugs are located from the bottom of the vial.

Claim Rejections - 35 USC § 102

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4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4, 12, 14, 21-22, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by LaBianca *et al* (UPS 4,733,773).

LaBianca *et al et al* disclose a storage container substantially as claimed. LaBianca *et al* teach the use of container body 26 comprising an outer surface, an open end 30, a closed bottom end 32 (column 1, lines 45-49). The vial comprising a plurality of integral anti-rotation lugs 68 about the outer surface of the cylindrical body (Fig. 2). Wherein the anti-rotation lug comprises a flat, longitudinally disposed surface extending radially outwardly from the body outer surface, which is substantially perpendicular to the body of the vial. Moreover, the surface of the plurality of anti-rotation lugs is accessible when the cap 24 is engaged with the neck of container 20 (Fig. 2). Additionally, the lugs have a lowermost edge that is located substantially remote from the bottom closed end of the vial (Fig. 2). The cap 24 comprises with a torque pattern formed on the outer surface. The torque pattern comprising a plurality of radially disposed ribs 140 (Fig. 2). Moreover, LaBianca *et al* discloses a seal means 42 disposed between the body and the cap, which seals fluid and maintains a slight positive pressure within the container to assist in long term preservation of contents (column 7, lines 34-60, Fig. 2). Note: that it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977

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F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the cited reference is believed to be reasonably pertinent to the particular problem with which the applicant was concerned, i.e. storage.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 2-3, 5-8, 10, 13, 15-20, 23, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaBianca *et al* (UPS 4,733,773) in view of Moore (USP 5,855,289).

LaBianca *et al* as previously discussed above, do not specifically recite a first alignment marker on the body on the cap and a second alignment marker on the body. Moore teaches a sample vial for use in an automated test apparatus comprising a body with an outer surface, an open end, a closed end, a cap 34 releasably engagable with the body. The cap comprising an outer surface and a torque pattern (Fig. 1 & 3) on the outer surface, wherein the torque pattern comprising a plurality of radially disposed ribs 64. The vial includes seals 54, 98 disposed

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between the body and the cap so as to be capable of forming a substantially fluid-tight seal therebetween. Moore teaches the cap comprising first screw threads 62 (Fig. 4) and a second mating screw thread 80 on the body (Fig. 1). Additionally, Moore teaches sample fluid level indicia 108 comprising an upper fill line and a lower fill line on the outer surface of the vial body (Fig. 1). Moore teaches a first alignment marker 110 on the body on the cap and a second alignment marker 108 on the body (column 7, lines 24-40). Moreover, Moore teaches a proximate structure comprising a storage container and vial sleeve 26 (Figs. 1-2).

LaBianca *et al* and Moore do not explicitly teach the use of the body and cap made from polypropylene, however would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the body and cap from an inert material, such as polypropylene, in order to ensure that the sample inside the vial will not react with the container or cap. Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Both LaBianca *et al* and Moore teach the creation of a fluid-tight seal formed between the body and the cap. However, neither LaBianca *et al* or Moore do disclose the specific range of torque between 5 and 50 inch-pound of torque applied to the cap. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have included in the invention of LaBianca *et al* and Moore the range of torque between 5 and 50 inch-pound of torque applied to the cap in order to ensure the cap and vial are properly sealed and prevent the leakage of a sample or air from the vial. Further, it has been held that where the general

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conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the invention of LaBianca *et al* a first alignment marker on the cap and a second alignment marker on the body, as taught by Moore, in order to insure a fluid-tight seal after a predetermined amount of rotational movement has been achieved between the cap and the vial. Thereby preventing the possibility of damaging the seal by over tightening the cap (column 7, lines 24-34).

9. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over LaBianca *et al* (UPS 4,733,773) and Moore (USP 5,855,289) as applied to claim 23, and further in view of Neeley *et al* (USP 5,164,575).

LaBianca *et al* and Moore previously discussed, do not teach a sample indicia comprising a bar code. However, such a means for identifying kinds of sample vials is considered conventional and usually required in the automatic analyzing art, see Neeley *et al*. Neeley *et al* teaches a sample indicia comprising a bar codes 7 & 51 (column 6, lines 46-68, Figs 4-5 & 8).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided in the modified apparatus of LaBianca and Moore, a bar code on the sample vial, as taught by Neeley *et al*, in order to identify the sample and make sure the proper sample is matched up with the patient (columns 2-3).

Response to Arguments

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10. Applicant's arguments with respect to claims 1-8, 10, 12-26 are have been considered but are moot in view of the new ground(s) of rejection. See above Office Action.

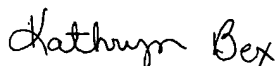
Conclusion


11. No claims allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

The fax number for the organization where this application or proceeding is assigned is (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.


P. Kathryn Bex
Patent Examiner
AU 1743
June 3, 2002


Jill Warden
Supervisory Patent Examiner
Technology Center 1700